Rockwell Laser Industries

RLI staff and consultants participate in the following laser safety activities:

American National Standards Institute Z-136 Standards:
- Executive Committee
- Committee Chairpersons:
  Control Measures
  Safety & Training
  Non-Beam Hazards
- Committee Memberships:
  Safe Use of Lasers
  Safe Use of Optical Fiber Communications Systems Utilizing Laser Diode and LED Sources
  Safe Use of Lasers in Health Care Facilities
  Test and Label Methods for Laser Protective Equipment
- Laser Safety Measurements and Instrumentation
- Safe Use of Lasers in Educational Institutions
- Safe Use of Lasers Outdoors

National Fire Protection Association:
- Technical Committee on Laser Fire Protection

SAE International:
- G10 Laser Safety Hazards Committee

International Standards
- **IEC**
  U.S. Delegate:
  TC/76 Laser Equipment
  Technical Advisors:
  WG 1: Radiation Safety
- **ISO**
  U.S. Delegate:
  TC 172/SC 9, Electro-Optics
  Chairperson:
  TC 172/SC 9/WG 3, Safety
  Committee:
  TC 172/SC 9:WG 5
  Specific Application Equipment

Canadian Standards Association:
- Technical Committee on Laser Safety

Laser Institute of America
- Board of Directors
- Laser Safety Committee
- International Laser Safety Conference

International Laser Display of America
- Laser Safety Committee

Society Memberships:
- American Industrial Hygiene Association
- American Society for Laser Medicine and Surgery
- American Society for Training and Development
- American Welding Society
- Association of Operating Room Nurses
- Health Physics Society
- Semiconductor Safety Association
- Society of Manufacturing Engineers

June 21, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Reference: Docket No. 93N-0044, Proposed Amendment to Laser Product Performance Standard

Gentlemen,

Enclosed are some comments for your consideration relative to the proposed amendment to the Laser Product Performance Standard. In general, I fully concur with the philosophy and intent of the proposed rule. There are some specific points upon which I offer my comments.

(b)(14) – The definition of "human access" as proposed does not reflect the suggested criterion for human access expressed in the background comments of the proposed rule. I strongly support the background comments indicated in the upper part of the third column of page 14181 of the referenced docket to change the definition to be based on eye exposure.

Table 7 - The background comments of the proposed amendment stated that the inclusion of LED products was no longer being considered. Table 7 contains the addition of LED products.

(d)(5) – The first paragraph calls for using the most restrictive of (d)(4)(i), (d)(4)(ii) or (d)(4)(iii). I think it should be "applicable", not the most restrictive.

(e)(3) – The background comments to the proposed amendment stated that the measurement criterion proposed was that agreed upon at the TC76/WG1 February 95 meeting in Washington. I believe at that meeting it was agreed that classification would be based on the measurement parameters given in (e)(3)(I)(A) and (e)(3)(I)(B). The measurement specified in (e)(3)(I)(C) would be used only to determine if a warning against the use of magnifying optics would be required in the user information. I see no statement in sections (d) or (e) to the fact that classification is based on (A) and (B).

93N-0044

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(f)(2) – General comment. IEC 60825 interlock requirements are less stringent. Is it the intent of CDRH to still require interlocks for products with less than 3B embedded levels of radiation? If so, I recommend that there be reconsideration to adopt the interlock requirements of IEC 60825-1.

(f)(2)(i) and (f)(2)(iii) – Both of these clauses appear to have the same stated conditions for access. If so, this does not make sense. It appears that (f)(2)(i) is the section that needs changing.

(f)(2) – Throughout this section there is the exclusion of reference to the Class 3B with not more than five times the AEL of Class 2. I believe this subset of 3B should be included with 3A in the interlock requirements.

(g)(4) – Although not part of the proposed amendment, I recommend that the information required in position 2 always include the wavelength. IEC requires the wavelength on a label, not "wavelength or laser medium". The laser medium alone could imply one of several wavelengths, or multiple wavelengths. The wavelength is the important parameter, not the type of laser. The type of laser could optionally be an additional piece of information in position 2.

(g)(5) – I recommend adding an optional wording for the aperture label, as does the IEC requirements. The optional wording simply being "LASER APERTURE". Many products have little space for an aperture label, and a reduction of text makes it easier to indicate where the aperture is located by using a font size that is legible from a reasonable distance. CDRH is permitting the use of IEC labels in this proposed amendment, so I feel it is appropriate that CDRH permit the short text version for the aperture label as part of the proposed amendment.

PART IV (Effective Date) – In past amendments, the effective date has been one year after publication for requirements that became more stringent, and immediately for those requirements that were relaxed. I recommend that the same apply for this amendment when published as a final rule.

I commend the agency and the personnel responsible for preparing this proposed amendment, and greatly appreciate the opportunity to submit the above comments for your consideration.

Respectfully submitted,

James F. Smith

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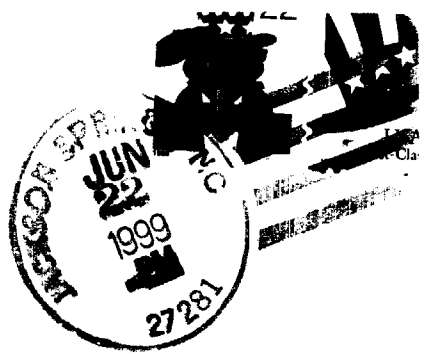

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To

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